REMARKS

It is acknowledged with appreciation that the prior Objection as to title terminology and the prior rejections under 103(a) and 102(a) have been withdrawn.

With regard to the new 102(e) rejection of Claims 51, 52, and 63-70 over WO 03/091226, Applicants respectfully traverse. Applicants first direct attention to page 2, lines 6-11 of the Specification as published (WO 2005/042414), where Applicants clearly state that the new forms IV & V are not the same solid form discovered in the prior reference, but were discovered in the course of development of an improved synthetic process.

It is also noted here that the invention is in the novel anhydrous polymorphs of the known compound (i.e. novel solid forms), and not in any separation/selection of a particular stereoisomeric form or a simple disclosure of a previously unknown/ undisclosed property or characteristic of the known compound (i.e. provision of physical data for the previously disclosed crystalline form), as is suggested in the rejection. However, it is well understood in the pharmaceutical field that great advantage can be found in the particular solid form of an active drug ingredient and that crystalline forms, particularly easily obtained/reproducible and easily handled crystalline forms are highly desired and often difficult to obtain. This is noted at page 2, lines 6-7 of the Specification as published. It is well understood that such improved properties in pharmaceutical active drug product solid forms can and often do have significant impact on the manufacturing and storage of pharmaceutical end products, as well as impact on activity of the therapeutic agent in vivo.

Next, Applicants draw attention to the Detailed Description in the Specification, particularly page 4, line 17 through page 12, line 2, wherein Applicants set forth just the type of data requested to prove the novelty of the invention over the prior solid form. Please note page 4, lines 25-30, stating:

> "Analysis of these parameters *[referring to X-ray powder diffraction and solid state NMR]* indicates that the crystalline form . . . originally resulting from the process described in . . . (WO03/091226)(Form I) is different than the two novel crystalline forms (Form IV and Form V) described herein. Variations in the characteristics of Form I versus Form IV or Form V are discussed in greater detail below."

The remainder of the referenced section then details the significant differences showing that Form IV and Form V are not Form I / Form I is neither Form IV nor Form V.

Thus it must be concluded that the Specification as filed provided ample description to demonstrate that the present invention is NOT described in the cited reference. Though the reference did not characterize the solid form described therein in terms of its crystalline properties, the present Application provided those characteristics of the referenced solid form and the significant differences in those same properties for the presently claimed invention, crystalline Form IV and Form V, as is requested by the present Office Action. It is noted that declaratory submission is not necessary and would only be redundant where, as here, the comparative x-ray powder diffraction and ^{13}C solid state NMR data are set forth in the Specification as filed.

Further, it is well understood in the crystallographic arts that small differences in crystallization conditions may have dramatic effects on the crystalline form produced (or NOT

produced as is often the case) and that there is simply no way *a piori* to expect, much less predict, success with any given crystallization method, IF any crystal form is obtained at all, let alone predict a specific crystalline form with beneficial properties over another form. In this regard, it is true that NO particular crystal form can be obvious prior to actually obtaining said crystal form. The physical characterization set forth in the Specification as filed demonstrates that the claimed forms are in fact novel over the referenced crystal form. It is therefore respectfully requested that the 102(e) rejection be withdrawn.

The Office Action's remarks regarding 103(c), reiterated from the prior Office Action of October 5, 2007, are noted. As previously asserted in the response dated November 6, 2007, page 6, the presently claimed invention and the subject matter in the WO 03/091226 reference were, at the time the present invention was made, commonly owned by or was subject to an obligation of assignment to Eli Lilly and Company. As such, 35 USC 103(c)(1) indeed applies.

It is believed that all rejections and objections have now been obviated or traversed. Reconsideration and withdrawal of the rejection is respectfully requested. It is respectfully submitted that the Claims as amended are in condition for allowance. Timely passage of the application to grant is kindly requested.

Respectfully submitted,

/R. Craig Tucker/
R. Craig Tucker
Attorney for Applicant(s)
Registration No. 45,165
Phone: 317-433-9829

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

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